K011775

AUG 3 0 2001

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

A. General Information

1. *Submitter's Name:*	FHC, Inc.
2. *Address:*	9 Main Street Bowdoinham, ME 04008
3. *Telephone Number:*	207-666-8190
4. *Contact Person:*	Frederick Haer
5. *Date Prepared:*	May 30, 2001
6. *Registration Number:*	1226598

B. Device

1. *Name:*	microTargeting® Drive System
2. *Trade Name:*	microTargeting® Drive System
3. *Common Name:*	Stereotactic Microdrive System
4. *Classification Name:*	Stereotactic Instrument
5. *Product Code:*	HAW
6. *Class:*	II
7. *Regulation Number:*	882.4560

C. Identification of Legally Marketed Devices

Name	*K Number*	*Date Cleared*
1. FHC microTargeting® Drive System	K003776	Feb. 23, 2001
2. Axon Instruments MP-1 Micropositioner	K99068	Nov. 3, 1999
3. Radionics CRW-FMD	K992721	Sept. 10, 1999
4. MSC µEEG µDrive Model 25/50	K991077	June 9, 1999

D. Description of Device

The microTargeting® Drive System with maTrix drive mount permits the accurate positioning of microelectrodes, stimulating electrodes, DBS™ electrodes, lesion electrodes, biopsy probes and other instruments in the brain and nervous system and is adaptable to all major stereotactic systems.

microTargeting™ Drive System Components

- microTargeting™ drive
- maTrix™ drive mount and lower guide
- maTrix™ guide bushings
- DBS™ holder with DBS/lesion stop
- verification probe
- sterilization case
- cleaning brushes
- hex wrench

microTargeting™ Drive System Accessories

- Radionics adaptor
- Leksell adaptor
- BrainLab adaptor
- Leibinger RM adaptor
- Leibinger ZD adaptor
- Leibinger Ost-Reg™ (STarFix™) adaptor
- NeuroMate™ adaptor
- single electrode insertion tube set
- array electrode insertion tube set
- lesion insertion tube kit and depth stops
- custom microelectrode depth stops

E. Intended Use Statement

The FHC microTargeting® Drive System is intended to be used with commercially available stereotactic systems for neurosurgical procedures which require the accurate positioning of microelectrodes, stimulating electrodes, DBS™ electrodes or other instruments in the brain or nervous system.

F. Technological Characteristics Summary

The FHC microTargeting® Drive System is substantially equivalent to the FHC, Inc. microTargeting® Drive System (K003776), Axon Instruments Guideline System 3000 MP-1 Micropositioner (K990683), the Radionics Cosman Robert Wells Functional Probe Microdrive (CRW-FMD) (K992721) and the Microrecording System Consultants µEEG™ Pro System 5000 µDrive Model 25/50 (K991077).

Differences that exist between these devices, relating to technical specifications, physical appearance, and design do not affect the relative safety and effectiveness of the microTargeting® Drive System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2001

Mr. Frederick Haer
President/CEO
FHC, Inc.
9 Main Street
Bowdoinham, Maine 04008

Re: K011775
Trade/Device Name: microTargeting® Drive System
Regulation Number: 882.4560
Regulatory Class: II
Product Code: HAW
Dated: May 30, 2001
Received: June 7, 2001

Dear Mr. Haer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011775

Device Name: microTargeting® Drive System

Indications For Use: The FHC microTargeting® Drive System is intended to be used with commercially available stereotactic systems for neurosurgical procedures which require the accurate positioning of microelectrodes, stimulating electrodes, DBS™ electrodes or other instruments in the brain or nervous system.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011775